DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22201 23rd Drive SE Bothell, WA 98021-4421 (425) 486-8788 Fax:(425) 483-4996 Industry Information: www.fda.gov/oc/industry	09/15/2009 - 09/18/2009
	FEI NUMBER 3003294857

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David Humphrey, President

FIRM NAME	STREET ADDRESS
Kirkman Group Inc., DBA Kirkman Laboratories Inc.	6400 Rosewood St
CITY, STATE, ZIP CODE, COUNTRY Lake Oswego, OR 97035-5392	TYPE ESTABLISHMENT INSPECTED Dietary Supplement Manufacturing

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

You did not prepare a written master manufacturing record for each unique formulation of a dietary supplement that you manufactured.

Specifically, you have not identified a document as the master manufacturing record as required.

OBSERVATION 2

You did not perform manufacturing operations under conditions and controls that protect against the potential for contamination.

Specifically,

1) Approximately 1/2 of the white paint directly above the product flow and adjacent to the exit spouts on the top of the (b) (4) tablet/capsule filling machine was missing. The paint appeared to have flaked off over a period of time.

2) Prior to and during the 25 mg alpha lipoic acid capsule filling procedure the production employee was observed leaning over the capsule filling plates and brushing his lab coat on the product contact surface. This occured when he was leaning over to set up the procedure and when reaching the product used for filling the capsules that was staged toward the back of the work table.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hugh A. Grimaldi, Consumer Safety Officer	DATE ISSUED 09/18/2009